

Natural Products & Quality Control of Herbal Drugs (208)



Lecture I

Orientation to Natural Products and Quality Control of Herbal Drugs

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- ❑ Welcome, fifth year students in the last term in our beloved Faculty of Pharmacy - Cairo University .. We wish you all the best.
- ❑ Many of us are asking "Why we are studying Pharmacognosy?" What are the benefits the world got from this science? why we study Pharmacognosy? It is almost extincted in the global pharmaceutical market?
- ❑ I'm honestly and briefly answering:
 - Do you know that the herbal medicine trade today in the world is about 95 billion dollars .. Egypt shares with almost nothing!
 - Do you know that about 80 percent of the existing drugs in pharmacy are either natural or derived from natural sources.
 - Almost all anti-cancer drugs and antibiotics are from natural sources
 - Ace Inhibitors medication group used for treatment of high blood pressure were inspired from natural source
 - Biguanides used in the treatment of hyperglycemia are inspired from a herb used in the treatment of poly-urea.
 - Group of Statins used to stop the biosynthesis of cholesterol in people who suffer from hardening of the arteries was derived from a natural source
 - Vitamins are derived from a natural source
 - To date 25% of the prescribed medications in prescriptions worldwide are herbal medicine
 - Atropine, morphine, taxol, digoxin, streptomycin, ephedrine, diosmin , glucose and thousands of other medications that are used today are from natural source
 - Nobel prize in 2015 were given for scientists discovered Artmesinin from Artmesia species (antimalarial) and Avermectin from fungi (Parasiticide - Filariasis)
 - We can assure that a natural product was beyond the discovery of each drug on the earth.
 - Natural products and quality control of herbal drugs course is very easy .. you can get excellent grade without major effort
- ❑ Let us confirm "we are not in need for private lessons".
- ❑ we can divide the course into two main parts

❑ The first part titled "Natural Products"

❑ Natural Products Part can be divided into 4 main courses.

- First course "Role of Natural Products in modern medicine". We are going to discuss many titles including "as pharmacists how can we transform a substance with weak therapeutic effect to a substance with strong therapeutic effect" .. How can we transform a toxic substance to a drug? .. How can we transform a substance without therapeutic effect to a drug? .. Many other examples will be studied also.
- Second course "Plant cell and tissue culture" in which we will study how can you produce active constituents of a plant in few days while it was produced in hundred year in the cultivated plant? .. How can you increase the production rate of active substances from the plant many times in a plant producing active substances with a small amount .. How can you save an important medicinal plant from extinction .. How can you produce giant plants and dwarf plants .. and many other items will be discussed.
- Third course "Plant biotechnology". We will know how can we produce plants resistant to the salinity of the earth and water scarcity by moving genes from desert plant to the new plant .. how can we transfer the gene responsible for the production of morphine from papaver to yeast and keep out yeast producing morphine .. We will know how can we construct natural or fictional gene and transfer it to the yeast or even to another plant to produce transgenic plant.
- Fourth course "Natural Drug Abuse". We will know many examples of abused drugs by addicts and athletes in races .. We will know why addicts and athletes use either depressant or stimulant drugs? .. We will know symptoms of the use and symptoms of poisoning of these abused drugs? .. more importantly you will know as a forensic pharmacist how can you identify these compounds with the modern methods.

❑ The second part is "Quality control of herbal drugs"

We will know how can we judge any herbal medicine .. Is it therapeutically effective or not? .. Is it safe medicine for patients? Is it toxic or non toxic? .. Is it pure or adulterated? .. Is it accepted for registration or not?

- ❑ Second part "Quality control" comprises five small courses
- ❑ The first course "Pharmacopoeias procedures for detecting the quality of herbal drugs". We will know The 9 Pharmacopoeia's steps, by them we can judge the medication "acceptable or unacceptable"? effective or ineffective? .. Safe or toxic? .. Pure or adulterated? .. These nine steps include:
 - 1- Sensory characters of the drug "e.g. Shape, taste and odour",
 - 2-Macroscopic and microscopic properties of the drug under the microscope.
 - 3- Qualitative Chemical tests to predict the pharmacology "Existence of the active constituent supposes the effectiveness of the drug and its absence makes the drug non effective".
 - 4- Quantitative determination of the active substances. The active constituents may be present but the concentration is lower than the minimum effective concentration and at that time the drug will be ineffective.
 - 5- Approximate analysis e.g. determination of the amount of moisture as the moisture indicates bad storage or to increase the weight of herbal medicine.
 - 6- Detect the potential contaminants e.g. presence of dangerous pollutants such as heavy metals and microbes, Aflatoxin, radioactive substances and pesticides.
 - 7- Physical identification of some constants for the existing single and pure material in the product e.g. boiling point, melting point and refractive index e.g. clove oil
 - 8- Determination of the biological activity e.g. a preparation supposed to contain aminoglycoside antibiotic and gave all the previous tests proving its existence but when conducting experiment on microbes we can find that it is biologically "very weak", because in fact, it can be hydrolyzed into the aglycone + sugar and we know that aglycone "non active" and Sugar "non active" also.
 - 9- Stability study: To prove the shelf life of the product.

- **Second course Gas Chromatography "GC"**. We will know that it is used during the application of the steps mentioned in the Pharmacopoeia to qualitatively and quantitatively analyze volatile substances with small molecular weight as a component in herbal medicine. We will know some of GC applications in the analysis of herbal pharmaceuticals and forensic sciences.
- **Third course High Performance Liquid Chromatography "HPLC"**. We will know that it is used during the application of the nine steps in the Pharmacopoeia to qualitatively and quantitatively analyze complex non-volatile, high-molecular-weight drugs. We will know some of HPLC applications in the analysis of herbal pharmaceuticals.
- **Fourth course: Structural Elucidation of Natural Products "Spectroscopy"**. We will know how to confirm the structure of any compound by using 5 instruments subsequently. The first device "AAS" gives us the Elemental analysis of the compound. We will know the percentage and proportion of each element, the Molecular formula and the number of un-saturations "double bond equivalence" in the compound. .. The UV device confirms the presence or absence of Conjugated systems in the compound .. IR device will identify the Nucleus of the compound from the fingerprint region, as well as the functional groups in the compound from the functional group region. Mass spectrometer will identify the Molecular weight of the compound. NMR device will identify the number of carbons, hydrogens, assortment and ordering of them with each other in the compound.
- **Fifth course: Ion Exchange Chromatography "IEC"** We will know what are the basics of this technique used to analyze polar materials qualitatively and quantitatively in medicine. .. How can you know the ingredients in the sample .. How can you know the amount of the ingredients in the sample. We will know some of IEC applications in the analysis of pharmaceutical and herbal medicines.

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توزيع درجات عملي النواتج الطبيعية و رقابة الجودة (70 درجة)

- 5 درجات على استكمال الرسومات و النتائج العملي في مذكرة العملي .. سيتم تصحيح المذكرة أولاً بأول في المعمل.
- 5 درجات على الانتظام و حضور المعامل .. أي معمل غياب يتم خصم نصف درجة.
- 10 درجات على شيت نظري عملي و سيكون شامل لنظري العملي في آخر العملي قبل امتحان العملي
- 10 درجات على امتحان عملي ال Phytochemical Screening .. سيعطوك في الامتحان Vegetable Powder و يسألك أن تكشف فيها عن مجموعتين من المواد الفعالة مثل هل بها Alkaloids and Saponins و ستكون درست هذه ال Tests و تدربت عليها طوال العام و عليك تسجيل النتائج التي تظهر امامك في الامتحان.
- 15 درجة على امتحان عملي ال Vegetable Powder .. ستعطى في الامتحان Vegetable Powder و يقول لك مثلاً هذه المفترض أن تكون Chamomile و المطلوب منك أن تؤكد بانها نقية Pure Chamomile .. أو Substituted بباودر آخر مثل ال Liquorice مثلاً .. أو مخلوطة (مغشوشة) Mixed or adulterated بباودر آخر مثل Starch و في هذه الحالة ستجد Chamomile + Starch تحت الميكروسكوب
- 10 درجات على امتحان عملي ال TLC Screening .. ستعطى في الامتحان TLC Plate و عينة خلاصة عشبية في زجاجة .. يقول لك مثلاً هذه المفترض أن تكون عينة ملوثة بال Strychnine .. المطلوب منك أن تؤكد بان بها Strychnine أو ليس بها Strychnine عن طريق انك بتعمل spotting لل sample against strychnine على ال TLC plate.
- 15 درجة على مشروع التخرج أو ال Project .. كل مجموعة من الطلبة (خمسة طلاب) يفترضوا انفسهم قد عملوا في شركة ادوية بعد التخرج .. و الشركة تريد انتاج دواء عشبي لعلاج مرض معين "سنعطى كل مجموعة المرض الخاص بهم" .. و على هؤلاء الطلبة أن يقترحوا Herbal Formula تتكون من 2-3 أعشاب لعلاج هذا المرض .. و عليهم أن يجهزوا ملف به ما يجب عمله من خطوات رقابة جودة حسب دستور الأدوية على هذا المستحضر بمكوناته كلها .. و عليهم أن يفترضوا انفسهم قد قاموا بكافة التحاليل الكاملة و ذلك بالاستعانة بكافة المراجع .. و تسجيل هذه النتائج لاثبات أن هذا المستحضر مطابق لدايتير الأدوية العالمية .. و أن يكتبوا في نهاية البحث (الخلاصة) بأن المستحضر يجب تسجيله في وزارة الصحة لان نتائج رقابة الجودة تؤكد بأنه يتماشى مع متطلبات دساتير الأدوية المعروفة .. سيقوم الطلبة بتقديم ملف وورد من 10 – 15 ورقة به كل الخطوات المطلوبة و نتائجها المفترضة و المطابقة لدايتير الأدوية .. و كذلك القيام بعمل باور بوينت لعرض خلاصة عملهم.

العملي سهل جدا و لا يحتاج إلى كورسات و لا لدروس خصوصية

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توزيع درجات امتحان النظري النواتج الطبيعية و رقابة الجودة على الادوية العشبية
(100 درجة)

Gas Chromatography (GC)

15 Marks

MCQs العام الماضي الاسئلة كانت

High Performance Liquid Chromatography (HPLC)

15 Marks

MCQs العام الماضي الاسئلة كانت

Structural Elucidation of Natural Products

15 Marks

MCQs العام الماضي الاسئلة كانت

Plant Biotechnology

15 Marks

MCQs العام الماضي الاسئلة كانت

The Pharmacopoeias Procedures for Detecting the Quality of Herbal Drugs

13 Marks

MCQs + True and False + Essays العام الماضي الاسئلة كانت

Plant Cell and Tissue Culture

9 Marks

Essay + Give reasons العام الماضي الاسئلة كانت

Ion Exchange Chromatography

9 Marks

Essay + Give reasons العام الماضي الاسئلة كانت

Natural Drug Abuse

9 Marks

Matching العام الماضي الاسئلة كانت

شكل اسئلة الامتحان هذا العام ستكون

MCQs + True & False + Essays + Give reasons + Matching + Complete

سيكون هناك محاضرة مراجعة النظري قبل امتحان آخر العام للتأكيد على شكل اسئلة الامتحان النظري و توزيع درجاته {حسب قواعد الجودة بالكلية}

النظري سهل جدا و لا يحتاج إلى كورسات و لا لدروس خصوصية